

Please also see a Claims Appendix with a complete listing of the claims as amended without correction marks.

REMARKS

The Office Action dated November 18, 2002 has been carefully reviewed. Claims 1, 3-6, 8-14, and 16-44 are pending. Claims 2, 7 and 15 have been cancelled. Claims 1, 3-6, 8-14 and 16-26 have been amended. Claims 27 through 44 have been added.

Reconsideration of the previous claim rejections is respectfully requested. Applicants thank the Examiner for her thorough and detailed remarks attached to the most recent Office Action.

Applicants believe that the amendments which have been made, along with the extensive nature of this response serve to put all the remaining claims in better condition for allowance. This is also true with respect to the canceled claims as well as with the claims which were amended or added. Given the above, it is specifically and respectfully requested that the Examiner enter and allow the claims as amended herein.

Claim Amendments

Applicants wish the Examiner to take note that their representation before the USPTO has recently changed. This change in representation has necessitated a review of the specification and prior prosecution activities by their new attorney. During this review it was determined that substantial amendments to the claims were needed to answer the Examiner's objections and to more fully present the invention for examination. Therefore each of the pending claims has been amended or has been added by Applicant in this Response. The pending claims as provided by Applicant are thus intended to be both part of a fully responsive reply to the Examiner's rejections and fully grounded in the teachings of the specification. MPEP §§ 608.01; 714.

The Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 3, 7, 11, 14-15, 17, 20 and 23-26 were rejected under 35 U.S.C. §112, second paragraph for being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Each of the objections to individual claims has been addressed through specific amendment to the relevant claims to clarify, particularly point out, and distinctly claim the subject matter of the invention. Claim 15 was cancelled.

Respectfully this rejection is traversed. The pending claims are now believed to comply with the provisions of 35 U.S.C. § 112, second paragraph. Thus, the Examiners objections based on §112, second paragraph are believed to be traversed. Reconsideration is respectfully requested.

The Rejections Under 35 U.S.C. §102(b)

SU 986411

Claims 1, 2, 4-6, 8-16, 18-22 and 26 are rejected under 35 U.S.C. §103(a) as being unpatentable over SU 986411 [IDS – AL]. In response to the Examiner's very thorough comments it should be noted at the outset that all of the existing independent claims within this group (claims 1 and 13) have been amended herein to address a variety of the Examiner's concerns as well as to ameliorate some structural and grammatical problems with the claims. Therefore Applicant requests reconsideration of the claims in light of these extensive amendments and claim additions. Given the analysis below, the Examiner's remaining objections to the claims as amended are respectfully traversed.

The fundamental requirement necessary to maintain a rejection based on anticipation is that each and every element of the claimed invention must be disclosed in a single prior art reference or embodied in a single prior art device or practice. In re Spada, 911 F.2d 705, 15 U.S.P.Q.2d 1655 (Fed Cir. 1990); See also, Minnesota Min. & Mfg. Co. v. Johnson & Johnson Orthopedics, Inc., 976 F.2d 1559, 24 U.S.P.Q.2d (Fed Cir. 1992). Moreover, anticipation requires **both an identity of elements and identity of process**, this SU 986411 is incapable of providing. Tyler Refrigeration v. Kysor Indus. Corp., 777 F.2d 687, 227 U.S.P.Q.177 (Fed Cir.

1986); Kalman v Kimberly-Clark Corp., 713 F.2d 760 (Fed. Cir. 1983), cert denied, 465 U.S. 1026 (1984). As was stated by the 9th Circuit:

"Unless all of the same elements are found in exactly the same situation and united in the same way to perform the identical function in prior pleaded art, there is no anticipation." Stauffer v. Slenderella Systems of California, Inc., 254 F.2d 127, 115 USPQ 347 (9th Cir. 1957).

It must be remembered that for anticipation to be properly found it is necessary that a previous disclosure express the virtually identical presence and function of the claimed methods and assays, thereby putting the invention in the hands of the public to practice. In re Wilder, 429 F.2d 447, 166 USPQ 545 (C.C.P.A. 1964); In re Brown, 329 F.2d 1006, 141 USPQ 245 (C.C.P.A. 1964); In re LeGrice, 301 F.2d 929, 133 USPQ 365 (C.C.P.A. 1962). This is clearly not done with the SU 986411 reference. Examiner states that with respect to the rejected claims the SU 986411 reference "is considered to be identical to the applicants' method for preserving mammalian sperm because they both comprise [sic] identical active steps and identical structural elements." (Office Action of November 11, 2002, p. 5 final paragraph). Moreover, as presented above, to anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently. While inherency itself may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient, all the elements must be present. Mehl/Biophile Int'l Corp. v. Milgrum, 192 F.3d 1362; 52 U.S.P.Q.2D 1303 (1999).

Therefore, in order to avoid rejection for anticipation, it is only necessary to show that independent base claims 1 and 13 each contain at least one element not disclosed in SU 986411. In reviewing the teachings of the SU 986411 reference, as guided by the prior legal precedent cited above, it is clear that the claims not only fail to recite the same elements, the actual function or "process" of utilizing the elements differs considerably. More to the point, amended claim 1 recites several elements not present or suggested in any of the teachings of SU 986411 including:

- + a) mixing said glycerol and said cooled first sample solution together to comprise a second sample solution;

4 b) lowering the temperature of [freezing] said [cooled sperm] second sample solution to a second temperature for a sufficient period of time to equilibrate glycerol and sperm.

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+ c) wherein said second sample solution further comprises an antibiotic compound.

+ d) wherein said sperm sample is cooled to said first temperature and maintained at said first temperature for 4 hours to 21 hours.

+ e) wherein said second sample solution is allowed to freeze at said second temperature.

None of the elements a-e above are disclosed in the SU 986411 reference. Therefore, it is respectfully proposed that the rejection of claim 1 for anticipation by the SU 986411 reference is overcome.

Likewise, claim 13 recites several elements not present or suggested in any of the teachings of SU 986411 including:

+ gels brought - f) lowering the temperature of said first cryoprotectant solution to a second temperature between -60°C and -90°C wherein said first cryoprotectant solution can freeze; and

+ g) wherein said first cryoprotectant solution further comprises an antibiotic compound.

+ h) wherein said sperm sample is cooled to said first temperature and maintained at said first temperature for 4 hours to 21 hours.

None of the elements f-g above are disclosed in the SU 986411 reference. Therefore, it is respectfully proposed that the rejection of claim 13 for anticipation by the SU 986411 reference is overcome.

Claims 2, 7 and 15 are canceled herein. Dependent claims 4-6, 8-12, 14, 16, 18-22, and 26 being dependent upon and further limiting independent claims 1 and 13, should also be allowable for those reason, as well as for the additional recitations they contain. Reconsideration

of the rejection of amended claims 1, 4-6, 8-14, 16, 18-22 and 26 under 35 U.S.C. § 102(b), is respectfully requested.

New claims 27-44 carry limitations similar to those found in independent claims 1 and 13 as the case may be. As they retain all the elements of the amended base claims from which they depend they should be allowable for this reason, as well as for the additional recitations they contain. Applicants therefore respectfully request favorable consideration claims 27 - 44 under 35 U.S.C. § 102(b), in view of the above amendments and remarks.

*Sikes et al.,
United States Patent 3,940,943*

Claims 13, 15-19 and 22 are rejected under 35 U.S.C. §102(b) as being anticipated by Sikes et al., (U.S. Patent No. # 3,940,943) (hereinafter the '943 patent) [IDS – AA]. Given the remarks already made and those that immediately follow, the rejection of the claims, as amended, is respectfully traversed. It should be again pointed out that in response to the Examiner's very thorough comments that the only independent claim under rejection by the '943 patent is claim 13 and that this claim has been amended herein to address a variety of the Examiner's concerns as well as to ameliorate some structural and grammatical problems with the claims. Therefore Applicant requests reconsideration of the claims in light of these extensive amendments and claim additions.

As stated above with regard to SU 986411 to avoid rejection for anticipation, it is only necessary to show that a claim contains at least one element not disclosed in a single prior art reference. Therefore, in order to avoid rejection for anticipation, it is only necessary to show that independent base claim 13 contains at least one element not disclosed in Sikes et al. In reviewing the claims of the Sikes et al., reference, as guided by the prior legal precedent cited above, it is clear that the claims not only fail to recite the same elements, the actual function or stepwise cooling "process" of the invention. Moreover, amended claim 13 recites at least two elements not present or suggested in either of the claims 1-2 of Sikes et al., including:

- a) wherein said sperm sample is cooled to said first temperature and maintained at said first temperature for 4 hours to 21 hours;

- b) wherein said first cryoprotectant solution further comprises an antibiotic compound.

Neither of the elements a nor b above are disclosed in the Sikes et al., reference. Therefore, it is respectfully proposed that the rejection of claim 13 for anticipation by the '943 patent is overcome. Importantly Sikes et al., also fails to disclose cryoprotectant components even remotely similar to those of the current invention. No mention is made of egg yolks, citric acid, or sugars like fructose. Essentially Sikes provides a bare methodology of collecting sperm but leaving the spermatozoa without a true cryoprotectant of the type present even in the art prior to the current invention. Respectfully, Sikes et al, represents the state of the art in 1975 without any of the improvements provided by the Applicants.

Claims 2, 7, and 15 are canceled herein. Dependent claims 16-19 and 22 being dependent upon and further limiting independent claim 13, should also be allowable for that reason, as well as for the additional recitations they contain. Reconsideration of the rejection of amended claims 13, 16-19 and 22 under 35 U.S.C. § 102(e), is respectfully requested.

New claims 27-44 have similar limitations to those discussed above, including claim 13 as the case may be. As they retain all the elements of the amended base claims from which they depend they should be allowable for this reason, as well as for the additional recitations they contain. Applicants therefore respectfully request favorable consideration claims 27-44 under 35 U.S.C. § 102(e), in view of the above amendments and remarks.

The Rejection Under 35 U.S.C. §103(a)

SU 986411, Sikes et al., and Royere et al.,

Claims 1-26 are rejected under 35 U.S.C. §103(a) as being unpatentable over the SU 986411 reference and the Sikes et al., (U.S. Patent No.# 3,940,943)(hereinafter the '943 patent) in view of Royere et al. The rejection of the claims, as amended, is respectfully traversed.

The basic considerations which apply to obviousness rejections under MPEP § 2141 are as follows:

- (1) the claimed invention must be considered as a whole;
- (2) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
- (3) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and
- (4) reasonable expectation of success is the standard by which obviousness is determined.

When the prior art itself fails to meet even one of the above criteria the cited art does not satisfy 35 U.S.C. § 103(a) and prevents the establishment of the required *prima facie* case of obviousness by the Examiner. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Rijckaert*, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). As pointed out below, the prior art not only fails to provide the suggestion, or incentive to combine but also fails to provide any reasonable expectation of success for the piecemeal combination of the prior art into something resembling the instant invention.

SU 986411

The SU 986411 citation is a patent from the former Soviet Union that provides some insight into the use of a cryoprotectant buffer and methodology somewhat similar in objective to the methods provided by the current invention. However, the concentrations of cryoprotectant components other than glycerol differ in amount and in concentration (e.g., fructose, citric acid, Tris, optimal concentration of egg yolk or the presence of antibiotics). Leading to the new buffer and sperm containing solutions of the invention with different characteristics and advantages. The Soviet reference provides no optimized concentrations, no protocols for mixture, and does not provide the stepwise cooling protocol of the current invention. This lack of guidance, lack of anything resembling “teaching” the invention is clear. Given this, and the controlling precedent cited above not only fails to anticipate the invention it also fails to render it obvious.

Moreover, SU 986411 fails to provide or teach the following:

- + a) mixing said glycerol and said cooled first sample solution together to comprise a second sample solution;

- b) lowering the temperature of said second sample solution to a second temperature for a sufficient period of time to equilibrate glycerol and sperm.
- c) wherein said second sample solution further comprises an antibiotic compound.
- d) wherein said sperm sample is cooled to said first temperature and maintained at said first temperature for 4 hours to 21 hours.
- e) wherein said second sample solution is allowed to freeze at said second temperature.

These deficiencies are not remedied by the application of the other citations provided by the Examiner. That is, though the SU 986411 reference and other citations are tasked to providing a solution to the same or similar problem the solutions each provides is significantly different.

Sikes et al.

? Sikes et al., does not provide what SU 986411 lacks. As already stated Sikes presents the state of the art as of 1975, and does not teach the invention as presented by Applicants. That is, it does not present a cryoprotectant buffer similar to the one employed by the Applicants. Nor can it teach (due to its remoteness in time) any combination with SU 986411.

Moreover, the patent states to add the cryoprotectant (glycerol) should be added immediately after collection. According to the current invention any glycerol use is added to the sperm sample only it has collected and cooled for 4 to 21 hours.

Thus, amended independent claims 1 and 13 and 24 cannot be obvious over Sikes et al., either alone or in combination with SU 986411 given these remarks and those already provided under the Examiner's anticipation rejections.

Royere et al.

Royere et al. also fails to provide what the SU 986411 and Sikes references lack. In fact Royere et al., is essentially a review article of the changes in the art over the last several decades. In this sense it catalogs what has gone before and in fact teaches against the methods of boyth Sikes and SU 986411, describing them as the "old methods" and not "truly rational" (Royere et al., Conclusions p. 557 relevant to anything more than 10 years old in the field, that is, available

prior to 1985)(SU 986411 published 1979, and Sikes et al., issued 1975), preventing any combination. Thus, Royere not only teaches away from SU 986411 and Sikes it's own limitations help to underscore the patentability of the current invention. No mention is made of the cryoprotectant composition provided by the current invention, no stepwise cooling system as provided by the claims is presented, no selection of antibiotics or concentration of egg yolk is taught. Rather Royere et al., simply reviews the field and points out prior deficiencies.

The present invention, as recited in amended independent claims 1, 13, and 24 offers the benefits of a novel structural methods and a different cryoprotectant composition. If the invention as recited were obvious, then those skilled in the art would have long since adopted this invention. However, according to the art of record, those skilled in the art have not adopted the present invention, and therefore do not get the benefit of the invention. Therefore, it is proposed that independent claims 1, 13 and 26 and those claims in turn dependent upon them, cannot be obvious.

Dependent claims 3-12, 14, 16-23, and 25-26 being dependent upon and further limiting independent amended claims 1, 13, and 26, should also be allowable for that reason, as well as for the additional recitations they contain. Applicants respectfully request reconsideration of the rejection of claims 1-26 under 35 U.S.C. § 103(a) in view of the above amendments and remarks.

New claims 27-44 have similar limitations to those discussed above, including claim 13 as the case may be. As they retain all the elements of the amended base claims from which they depend they should be allowable for this reason, as well as for the additional recitations they contain. Applicants therefore respectfully request favorable consideration claims 27-44 under 35 U.S.C. § 103(a), in view of the above amendments and remarks.

The Commissioner is authorized to charge any fee which may now or hereafter be due for this divisional application to GTC Biotherapeutics' Deposit Account No. 502092.

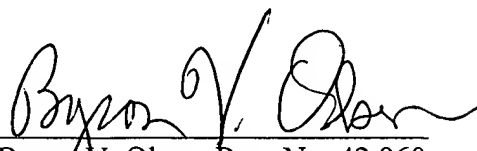
Applicants respectfully submit that the pending claims of this application are in condition for allowance, and that this case is now in condition for allowance of all claims therein. Such action is thus respectfully requested. If the Examiner disagrees, or believes for any other reason

that direct contact with Applicant's attorney would advance the prosecution of the case to finality, the Examiner is invited to telephone the undersigned at the number given below.

Early and favorable action is earnestly solicited.

Respectfully Submitted,

Date: 5/19/03

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